VOI BOSC Review Agenda and Charge Questions

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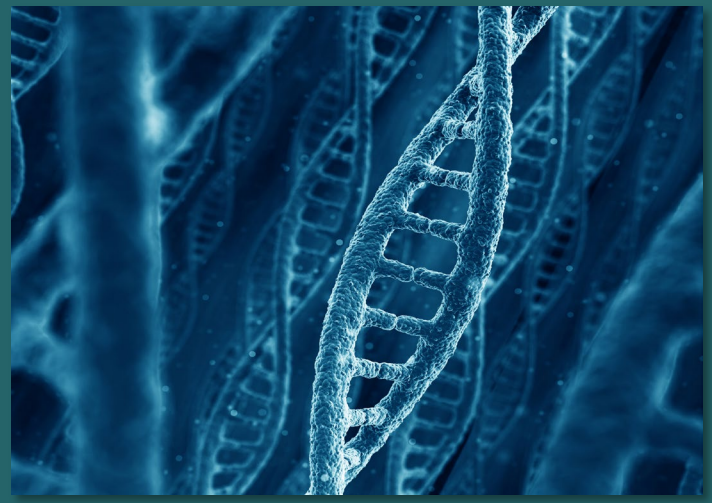

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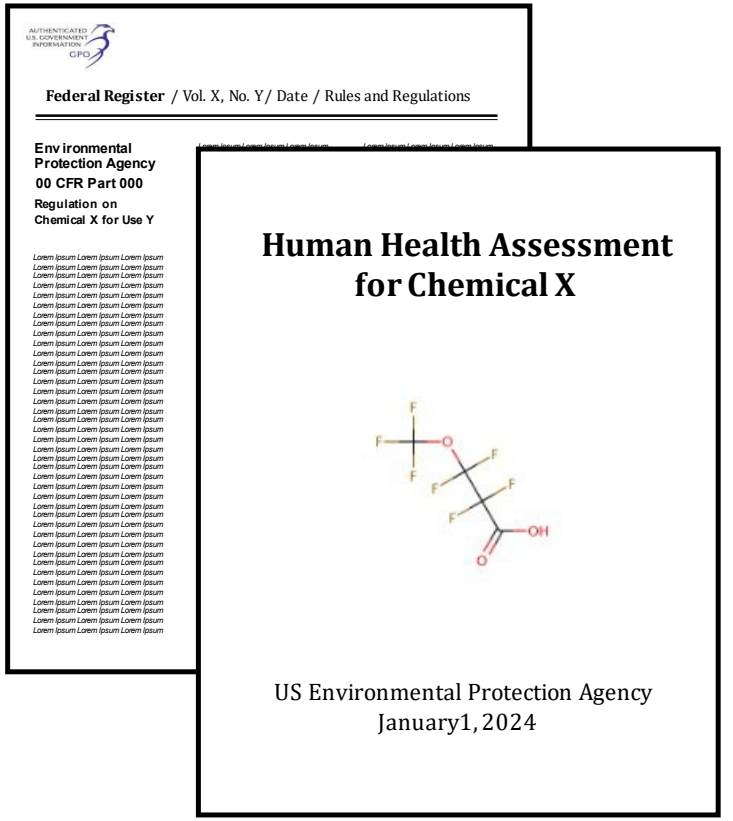
The Crux of the Issue



Trade-Offs Quantified in a Value of Information (VOI) Framework

DOI: 10.1111/risa.13931

ORIGINAL ARTICLE

A value of information framework for assessing the trade-offs associated with uncertainty, duration, and cost of chemical toxicity testing

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Abstract
A number of investigators have explored the use of value of information (VOI) analysis to evaluate alternative information collection procedures in diverse decision-making contexts. This paper presents an analytic framework for determining the value of toxicity information used in risk-based decision making. The framework is specifically designed to explore the trade-offs between cost, timeliness, and uncertainty reduction associated with different toxicity-testing methodologies. The use of the proposed framework is demonstrated by two illustrative applications which, although based on simplified assumptions, show the insights that can be obtained through the use of VOI analysis. Specifically, these results suggest that timeliness of information collection has a significant impact on estimates of the VOI of chemical toxicity tests, even in the presence of smaller reductions in uncertainty. The framework introduces the concept of the expected value of delayed sample information, as an extension to the usual expected value of sample information, to accommodate the reductions in value resulting from delayed decision making. Our analysis also suggests that lower cost and higher throughput testing also may be beneficial in terms of public health benefits by increasing the number of substances that can be evaluated within a given budget. When the relative value is expressed in terms of return-on-investment per testing strategy, the differences can be substantial.

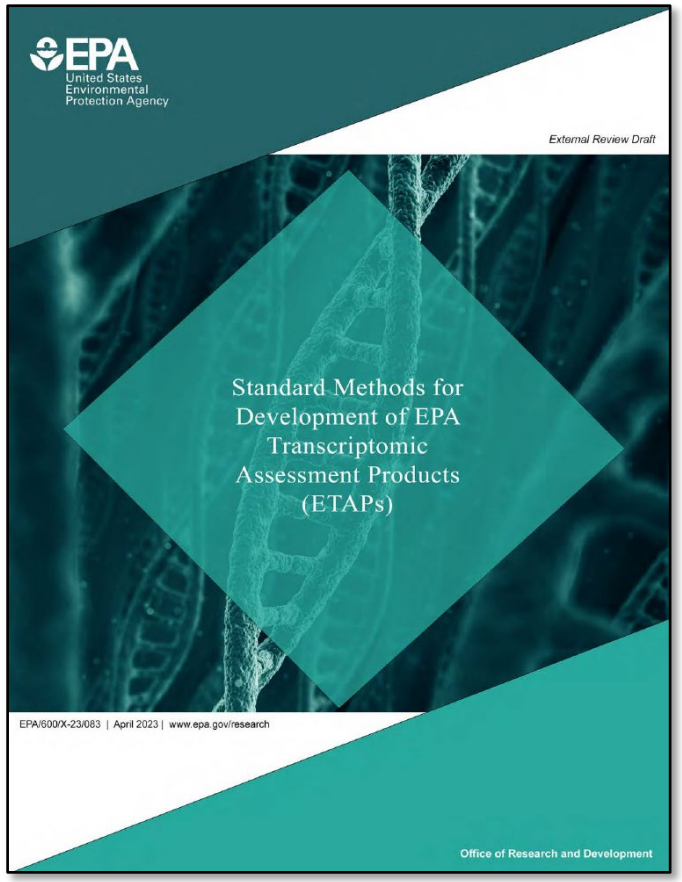
KEYWORDS
cost of delay, return on investment, risk decision making, social cost, toxicity testing, value of information

1 | INTRODUCTION

Evidence-based risk assessment has become a cornerstone of public and population health risk decision making, integrating evidence on toxicity and exposure from multiple evidence streams. When the available evidence is insufficient to allow a decision to be made with confidence, consideration can be given to gathering additional evidence to strengthen the evidence base. The present paper focuses on the use of value of information (VOI) analysis to evaluate the utility of gathering additional evidence on the toxicity of chemicals. Specifically, we present a VOI analytic framework that builds on previous methodological work in this field, explicitly incorporating the value of additional test data resulting from reductions in the uncertainty in estimates of a chemical's toxicity, the cost of delay in decision making that results

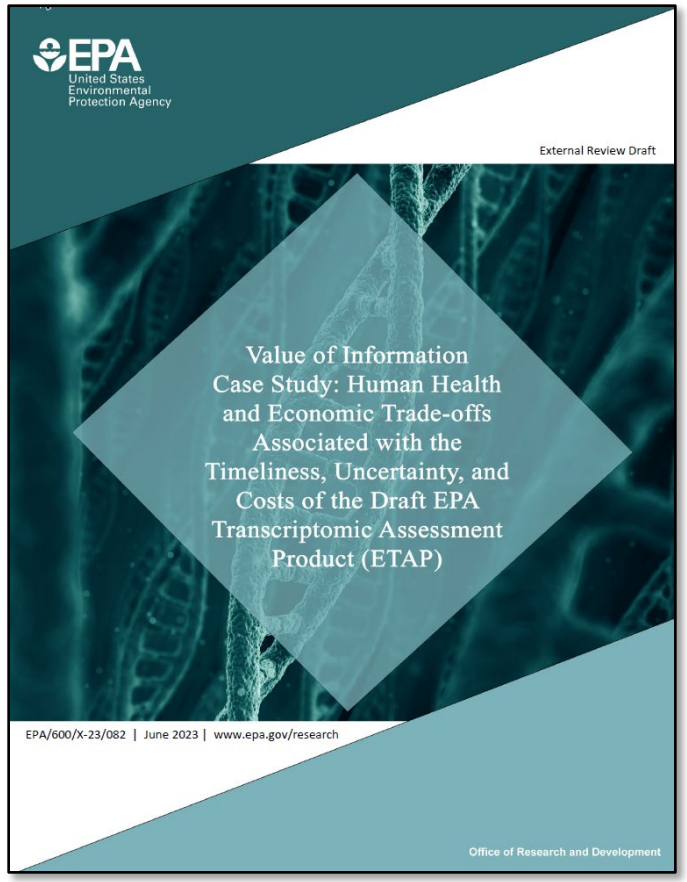
VOI framework that incorporates the main components of chemical risk assessment and time

Application of the Value of Information Framework to Evaluate a Draft New Human Health Assessment Product



(Not part of this BOSC Review)

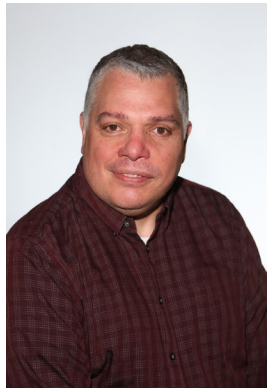
- Standardized experimental design and data analysis
- Templated reporting
- Stream-lined review process
- Target time from initiation to release is < 9 months
- Specific data poor decision context



VOI Team Introductions

Rusty Thomas
(EPA CCTE)

Alison Harrill
(EPA CCTE)



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Chris Gonzales
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Greg Paoli
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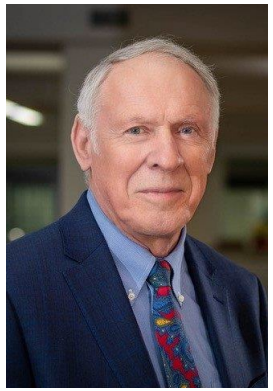

Dan Krewski
(RSI)

VOI BOSC Review Agenda – Day 1

Time	Duration	Topic	Speaker
11:00-11:10 am	10 minutes	Welcome	Maureen Gwinn
11:10-11:20 am	10 minutes	Introduction of the Panel	Tom Tracy
11:20-11:40 am	20 minutes	Day 1 Agenda, Introduction of VOI Team, and Charge to the Panel (Review Charge Qs)	Rusty Thomas
11:40-12:00 pm	20 minutes	Background on Underlying Toxicity Testing and Human Health Assessment Needs	Alison Harrill
12:00-1:00 pm	60 minutes	Value of Information Analyses and Overview of Published Framework	Greg Paoli, Risk Sciences International (RSI)
1:00-1:30 pm	30 minutes	Break	
1:30-2:00 pm	30 minutes	Design of the Case Study	Alison Harrill
2:00-2:45 pm	45 minutes	Parameterization of the VOI Models for the Case Study	Greg Paoli, RSI
2:45-3:00 pm	15 minutes	Break	
3:00- 3:45 pm	45 minutes	Case Study Results	Shintaro Hagiwara, RSI
3:45-4:00 pm	15 minutes	Summary and Conclusions	Alison Harrill
4:00-4:50 pm	50 minutes	Questions from Panel	Co-chair: Julia Rager
4:50-5:00 pm	10 minutes	Wrap Up	Rusty Thomas

VOI BOSC Review Agenda – Day 2

Time	Duration	Topic	Speaker
11:00-11:10 am	10 minutes	Welcome Back	Annette Guiseppi-Elie
11:10-12:00 pm	50 minutes	Public Comment Period	Facilitator: Tom Tracy
12:00-12:30 pm	30 minutes	Break	
12:30-1:30 pm	60 minutes	Questions from Panel	Co-chair: George Grey
1:30-3:30 pm	120 minutes	Break up into Charge Question Groups (closed session)	Co-chair: Julia Rager
3:30-3:45 pm	15 minutes	Break	
3:45-4:45 pm	60 minutes	Report out and Charge Question Discussions	Co-chair: George Grey
4:45-5:00 pm	15 minutes	Wrap Up and Close meeting	Rusty Thomas

Structure for Responses to Charge Questions

- Response categories
  - **Tier 1: Recommendations** – Responses necessary to adequately support scientific basis of the VOI case study or to improve clarity of the presentation.
  - **Tier 2: Suggestions** – Responses for EPA to consider to strengthen the scientific basis of the VOI case study or to improve clarity of the presentation.
  - **Tier 3: Future Considerations** – Advice you may have for scientific exploration or research to inform future work.

Review of Charge Questions

1. The general VOI framework developed by Hagiwara et al. (2022) for comparing human health and economic benefits of toxicity-testing methodologies was adapted for application to this case study. Please comment on the extent to which the VOI framework and decision model are clearly described and the extent to which it provides sufficient representation of chemical risk assessment and decision making that facilitates a reasonable comparison of toxicity testing and human health assessment processes.
2. Most of the inputs to the decision model used in the case study were drawn from published literature sources, experimental measurements, or peer-reviewed computational models. Please comment on the extent to which the input parameters are clearly described and represent the best available sources for use in the case study.

Review of Charge Questions

3. The baseline scenarios and sensitivity analyses were intended to represent the range of chemical characteristics and potential uncertainties that could be encountered in applying the toxicity testing and human health assessment approaches to data poor chemicals under EPA regulatory purview. Please comment on the extent to which the baseline scenarios and sensitivity analyses are clearly described and provide reasonable representation of the range of chemical characteristics and potential uncertainties that could be encountered in this context.
4. Please comment on the overall conclusions of the VOI case study that, under the exposure scenarios and assumptions considered, the ETAP is more frequently preferred over the traditional toxicity testing and human health approach for more rapidly and cost effectively evaluating chemicals with no existing toxicity testing or human health data.

Thank You

VOI Team, Executive Direction, and Implementation

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Madison Clark
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Kathie Dionisio
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Annette Guiseppe-Elie
Chris Gonzales
Maureen Gwinn
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Alison Harrill

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